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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,537	08/11/2006	Rose-Marie Dannenfelser	33396-US-PCT	7008
1095	7590	03/19/2008		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER PACKARD, BENJAMIN J	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 03/19/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/574,537	DANNENFELSER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 6-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1pg (03/31/2006)</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I (claims 1-16 drawn to pharmaceutical compositions) and species of cosolvent = polyethylene glycol 400, surfactant = polysorbate, and antioxidant and buffer not elected present in the reply filed on 01/18/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The election/restriction is made FINAL.

Claims 6-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3** are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimoto et al (US 6,291,523, see Applicants' IDS dated 03/31/2006 Cite AA).

Fujimoto et al discloses the compound (or pharmaceutically acceptable salt) of the present application for use for the treatment of conditions which are responsive to the inhibition of COX-2 (col. 4 lines 45-52 and col. 17 line 46). Injectable compositions are preferably **aqueous** isotonic solutions or suspensions where the compositions may contain adjuvants, such as preserving, stabilizing, wetting or emulsifying agents (i.e. surfactants), solution promoters (i.e. such as such as a co-solvent), salts for regulating the osmotic pressure and/or buffers. (col. 1 4, 1. 32-40).

**Claims 1-3 and 5** are rejected under 35 U.S.C. 102(a) as being anticipated by Lu et al (US Pregrant Pub 2003/0161867, filed May 30, 2002, see Applicants' IDS dated 03/31/2006 Cite AB).

Lu et al discloses compositions comprising COX-inhibitors, e.g. lumiracoxib or pharmaceutically acceptable salts thereof. The compounds are solubilized in a carrier, e.g. polyethylene glycol (73, 741) and the compositions may comprise a cosolvent 1821, e.g. polyoxyethylene castor oil or polysorbate. Also, tables 11, 14, 18 and 24 disclose compositions comprising a COX-inhibitor (or salt thereof), polysorbate and propylene glycol.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al (US Pregrant Pub 2003/0161867, filed May 30, 2002, see Applicants' IDS dated 03/31/2006 Cite AB, as applied to claims 1-3 and 5 above).

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Lu et al discloses compositions comprising COX-inhibitors, e.g. lumiracoxib or pharmaceutically acceptable salts thereof. The compounds are solubilized in a carrier, e.g. polyethylene glycol (73, 741) and the compositions may comprise a cosolvent 1821, e.g. polyoxyethylene castor oil or polysorbate. Also, tables 11, 14, 18 and 24 disclose compositions comprising a COX-inhibitor (or salt thereof), polysorbate and propylene glycol.

Lu et al does not specifically disclose propylene glycol 400.

One of ordinary skill in the art would recognize the limited number of propylene glycols and with simple testing could optimize the solution, finding the propylene glycol with the optimum properties. Therefore, it would be obvious to one of ordinary skill in the art to choose propylene glycol 400 where the property desired is simply solubility of the drug and varying the propylene glycol composition will achieve that same effect.

**Claims 1-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Jost-Price et al (US Pregrant Pub 2004/0220153, as applied to claims 1-5 above).

Jost-Price et al discloses aqueous solutions (paragraph 248) where the COX-2 inhibitor is lumiracoxib (claims 9, 29, and 60). Common excipients are taught which include polysorbate (paragraph 237) and PEG 400 (paragraph 0244).

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such “picking and choosing” within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference

does not provide any motivation to select this specific combination of variables, anticipation cannot be found.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients from within Price et al's disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

### ***Conclusion***

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No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-3:45 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/  
Patent Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612